

### **REMARKS**

The Office Action mailed May 13, 2008 has been carefully considered and the following is responsive thereto.

#### **Rejection under 35 USC 103**

At page 5 of the Office Action, the Examiner maintained the rejection of claims 1-2, 5-22, 29-34 and 36-38 under 35 USC 103 as unpatentable over Gilleland et al. (U.S. Patent 6,375,981) in view of Colegrove (U.S. Patent 6,509,311). In the present Office Action the Examiner alleged that it would be obvious to one of ordinary skill in the art to use the propylene glycol alginate taught by Colegrove in a formulation that requires gel or film formation as taught by Gilleland et al. with a reasonable expectation of success in view of the disclosures of Colegrove that propylene glycol alginates can produce gels of various textures, and knowledge in the art that capsule shells can be made of soft, elastic gels or hard gels.

Applicants again traverse this rejection. Applicants incorporate by reference their remarks concerning this rejection in the response filed March 6, 2008.

Claim 1 as presently amended is directed to a homogeneous, thermoreversible gel film comprising a film forming amount of a water soluble, thermoreversible alginate and optionally at least one of a plasticizer, a second film former, bulking agent, and a pH controlling agent, wherein the alginate is at least one of propylene glycol alginate or salts of such alginate and combinations thereof. Claims 2, 5-35 and 38 (in part) depend directly or indirectly from claim 1. Claim 36 is directed to a homogeneous, thermoreversible gel film consisting of a film forming amount of a water soluble thermoreversible alginate, flavorant and water. Claims 37 and 38 (in part) depend from claim 36.

Claims 1-2, 5-22, 29-34 and 36-38 are not obvious in view of Gilleland et al. and Colegrove. Persons skilled in the art would have no motivation to try to form gel films and capsules using propylene glycol alginate, or a reasonable expectation they would be successful in forming gels and capsules with this type of alginate. The present application at page 7, last paragraph, discloses that propylene glycol alginate was generally known in the art as a non-gelling alginate. Colegrove mentions at column 1, lines 20-26 that propylene glycol alginates are used in such products as salad dressings, and for stabilization of beer foam, but such alginates

had not been considered for gel formation, or for the production of useful gels. Colegrove was able to obtain gels using propylene glycol alginates, but there is no disclosure or suggestion that the gels would be suitable for forming gel films or capsules. Colegrove discloses a room deodorant gel prepared with propylene glycol alginate (Example 7), as well as six other examples of gels formed with propylene glycol alginate, one of which was unstable (Example 5).

At the time the present invention was made, persons skilled in the art would not consider substituting propylene glycol alginate for the starch in the capsules of Gilleland because there was no indication that this type of alginate could even be used to form gel films and capsules, and every indication that such a use would be unsuccessful because propylene glycol alginate was generally known in the art as a non-gelling alginate. It was therefore surprising that propylene glycol alginate provides a homogeneous, thermoreversible gel film having significant film strength.

Additionally, there is no disclosure or suggestion in the combined teachings of Gilleland et al. and Colegrove et al. of a gel film consisting of a film forming amount of a water soluble thermoreversible alginate, flavorant and water as claimed in claims 36-38.

Claims 1-2, 5-22, 29-34 and 36-38 are not obvious in view of Gilleland et al. and Colegrove et al. Withdrawal of this section 103 rejection is again respectfully requested.

### **Rejection under 35 USC 103**

At page 11 of the Office Action, the Examiner rejected claim 35 under 35 USC 103 as being unpatentable over Gilleland et al. (U.S. Patent 6,375,981) in view of Colegrove (U.S. Patent 6,509,311) and further in view of Cade et al. (U.S. Patent 6,517,865). The Examiner alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the film forming thermoreversible composition comprising alginate as the gum, as suggested by Gilleland, use the propylene glycol alginates as the gel film forming material, as suggested by Colegrove, and further combine it with the film composition without plasticizer, as suggested by Cade to produce the instant invention.

Applicants traverse this rejection. Claim 35 is directed to the homogeneous, thermoreversible gel film of claim 1, wherein the gel film does not contain a plasticizer. In claim

1, as presently amended, the alginate is at least one of propylene glycol alginate or salts of such alginate and combinations thereof.

Gilleland discloses the use of modified starch as a replacement for gelatin in soft gel films and capsules. The film forming compositions of Gilleland et al. comprise modified or waxy starch, gum and plasticizers. Alginates are mentioned as one example of a preferred gum. Gilleland does not disclose the use of propylene glycol alginate.

Colegrove discloses a gel system comprising propylene glycol alginate and an aluminum salt. The gels are disclosed as useful for personal care formulations such as a room deodorant gel. Colegrove discloses a room deodorant gel in a container, wherein the gel was prepared with propylene glycol alginate (Example 7), as well as six other examples of gels formed with propylene glycol alginate, one of which was unstable (Example 5).

Cade et al. discloses polymer compositions suitable for film forming for hard and soft capsules comprising water soluble cellulose ethers, hydrocolloids and sequestering agents. At column 2, lines 10-29, Cade et al. mentions that suitable hydrocolloids include such items as synthetic gums which are capable of gelling without the addition of alkaline or alkaline earth metal ion. The preferred hydrocolloid is gellan gum, which can be mixed with other materials such as alginates, and various types of gums other than gellan gum. Cade et al. does not disclose the use of propylene glycol alginate.

Claim 35 is not obvious in view of Gilleland et al., Colegrove and Cade et al. Persons skilled in the art would have no motivation to try to form gel films and capsules using propylene glycol alginate, or a reasonable expectation they would be successful in forming thermoreversible gel films and capsules with this type of alginate, much less thermoreversible gel films that do not contain a plasticizer.

There is no disclosure in either Gilleland et al. or Cade et al. of the use of propylene glycol alginate in gel films and capsules. This is not surprising, since, as disclosed in the specification at page 7, last paragraph, propylene glycol alginate was generally known in the art at the time the present invention was made to be a non-gelling type of alginate. Colegrove discloses gel systems comprising propylene glycol alginate and aluminum salts, however, there is no disclosure or suggestion that such gels could be used to form gel films and capsules. At the time the present invention was made, persons skilled in the art would not consider substituting

propylene glycol alginate as disclosed in Colegrove for the starch in the capsules of Gilleland because there was no indication that propylene glycol alginate could even be used to form gel films and capsules, and every indication that such a use would be unsuccessful. It was therefore surprising that propylene glycol alginate provides a homogeneous, thermoreversible gel film having significant film strength.

Claim 35 is not obvious in view of Gilleland et al., Colgrove and Cade et al. Withdrawal of this section 103 rejection is respectfully requested.

**Double Patenting Rejection**

At page 13 of the Office Action, the Examiner maintained the rejection of claims 1, 2, 8-11, 17, 22 and 35 on the grounds of nonstatutory obviousness-type double patenting as unpatentable over claims 1, 10-15 and 23-25 of copending Application No. 10/824,957.

Applicants again request that this rejection be held until such time as notice of patentable subject matter has been received in the applications. Applicants will file an appropriate terminal disclaimer at that time if necessary.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is requested and an early Notice of Allowance is earnestly solicited.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 10884-00010-US from which the undersigned is authorized to draw.

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Respectfully submitted,

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